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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,049	01/18/2006	David M. Hammerbeck	C1271.70077US00	1834

23628 7590 12/30/2010
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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1613	

MAIL DATE	DELIVERY MODE
12/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,049	HAMMERBECK ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,11,12,15-21,35-37,39-41,43, 45 and 49* is/are pending in the application.

4a) Of the above claim(s) *36,37,41,43 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,11,12,15-21,35 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner acknowledges receipt of request for continued examination under 37 CFR 1.114 filed 10/21/2010; amendment and remarks filed 11/19/2010. Claims 1, 2, 11, 12, 15-19 and 35 are amended. No claim is canceled or added. Claims 1-7, 11, 12, 15-21, 35-37, 39, 41, 43, 45 and 49 are pending. Claims 36, 37, 39, 41, 43 and 45 are withdrawn from consideration.

Response to Arguments

2. Previous objection that are not reiterated herein are withdrawn in view of the amendment.

Continued Examination Under 37 CFR 1.114

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/21/2010 and 11/19/2010 has been entered.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-7, 15-21 and 35 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hedenstrom et al. (US 6,706,728) or Miller et al. (US 6,083,505) in view of Gizurarson (US 6,647980) and further in view of Kublik et al. ("Nasal delivery systems and their effect on deposition and absorption" in Advanced Drug Delivery Reviews, 29 (1998), pp 157-177).

7. Hedenstrom: Hedenstrom discloses method of treating conditions associated with mucosal surface with a composition comprising immune response modifier or pharmaceutically acceptable salts of claims 1, 2, 11, 12, 15-21 and 35 and 49 (abstract; column 3, lines 34-43; column 12, line 34 to column 23, line 2); the composition may contain surfactants (column 23, line 63 to column 24, line 9), viscosity enhancing agents such as carbomer/Carbopol (column 24, lines 10-19; column 8, lines 18-38), chelating agent, preservative and water (column 24, lines 20-47). The mucosal surfaces in Hedenstrom include buccal, gingival, nasal, tracheal, bronchial, gastrointestinal, rectal, urethral, urethral, vaginal, cervical, uterine, etc (column 24, line 65 to column 25, line 6). The carbopol/carbomer viscosity enhancing agents meet the limitation of claims 1 and 3-7.

8. While Hedenstrom teaches the presence of viscosity enhancing agent and while viscosity is a property of the composition, Hedenstrom does not specifically say that the formulation is administered with spray device.

9. However, Gizurarson teaches that active agents are administered to the nostrils by using nasal spray device (abstract; column 2, lines 25-51, 59, 60; column 6, line 63 to column 7, line 25) and that the nasal composition is a liquid (column 7, lines 58-60). Gizurarson also teaches that the viscosity enhancing agent should be present in such amount as to provide sufficient dynamic viscosity to the preparation in such a way that the dynamic viscosity of the composition measured at 25 ^{o}C is higher than the dynamic viscosity of water which is about 1 cP; Gizurarson then suggested that the dynamic viscosity should be at least 5 cP or in the range of 5-300 cP or 10-75 cP or 10-50 cP. A dynamic viscosity of 5 cP or 10-75 cP or 10-50 cP are all less than 100 and anticipates the recited viscosity in claim 1.

10. Furthermore, Kublik teaches that pharmaceutical nasal preparations on the market are solutions and emulsions and suspensions and are delivered by metered dose pump sprays that provides defined dose and high dosing accuracy (paragraph 4.1.5).

11. Therefore, taking the teachings of Hedenstrom, Gizurarson and Kublik, one having ordinary skill in the art at the time the invention was made would be motivated to deliver the nasal composition of Henderson by the device of Gizurarson and Kublik since the nasal spray device allows the application of defined dose with high dosing accuracy and typical spray pattern. While viscosity is an inherent property, Gizurarson discloses that the viscosity enhancing polymer should be used in amounts that would provide viscosities of 5 cP, 10-75 cP and 10-50 cP so that the claimed viscosity is rendered obvious and absent factual showing of

unexpected result, a claimed viscosity of less than 100 does not patentably distinguish the disclosed viscosity of 5 cP, 10-75 cP and 10-50 cP.

12. The recitation that the "formulation is for delivery of an immune response modifier to the nasal passage of a subject" is an intended use of the formulation at the intended route of administration.

13. Miller: Miller discloses pharmaceutical composition comprising immune response modifier of claims 1, 2, 11, 12, 15-21 and 35 and carriers (see column 3, lines 4-11; column 8, lines 61-67; claims 1 and 12) and which is administered nasally (column 9, line 2).

14. Viscosity is an inherent property of the composition. Miller does not teach the pharmaceutical carriers of claims 1 and 3-7.

15. However, Gizurarson teaches that active agents are administered to the nostrils by using nasal spray device (abstract; column 2, lines 25-51, 59, 60; column 6, line 63 to column 7, line 25) and that the nasal composition is a liquid (column 7, lines 58-60). Gizurarson also teaches that the viscosity enhancing agent should be present in such amount as to provide sufficient dynamic viscosity to the preparation in such a way that the dynamic viscosity of the composition measured at 25 ^{o}C is higher than the dynamic viscosity of water which is about 1 cP; Gizurarson then suggested that the dynamic viscosity should be at least 5 cP or in the range of 5-300 cP or 10-75 cP or 10-50 cP. A dynamic viscosity of 5 cP or 10-75 cP or 10-50 cP are all less than 100 and anticipates the recited viscosity in claim 1.

16. Furthermore, Kublik teaches that pharmaceutical nasal preparations on the market are solutions and emulsions and suspensions and are delivered by metered dose pump sprays that provides defined dose and high dosing accuracy (paragraph 4.1.5).

17. Therefore, taking the teachings of Miller, Gizurarson and Kublik, one having ordinary skill in the art at the time the invention was made would be motivated to deliver the nasal composition of Henderson by the device of Gizurarson and Kublik since the nasal spray device allows the application of defined dose with high dosing accuracy and typical spray pattern. While viscosity is an inherent property, Gizurarson discloses that the viscosity enhancing polymer should be used in amounts that would provide viscosities of 5 cP, 10-75 cP and 10-50 cP so that the claimed viscosity is rendered obvious and absent factual showing of unexpected result, a claimed viscosity of less than 100 does not patentably distinguish the disclosed viscosity of 5 cP, 10-75 cP and 10-50 cP.

18. The recitation that the "formulation is for delivery of an immune response modifier to the nasal passage of a subject" is an intended use of the formulation at the intended route of administration.

19.

Response to Arguments

20. Applicant's arguments filed 11/19/2010 have been fully considered but they are not persuasive.

21. Applicant argues that Miller does not teach that the solution is sprayable; that Miller's injectable composition does not contain an immunogen.

22. Response: Miller teaches that its composition can be administered nasally as described in the rejections above. It is known in the art (see Kublik and Gizurarson) that composition that are administered to the nostrils are done by pump spray of spray device with the advantage that the nasal spray device allows the application of defined dose with high dosing accuracy and typical spray pattern. Miller teaches nasal administration and the fact that the injectable example does not contain immunogen, it is noted that the prior art is not limited to the example and rather, the reference as a whole must be considered. Furthermore, it is known in the art that spray devices are used to deliver drug to the nostrils (see Gizurarson).

23. No claim is allowed.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Y. Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1618